4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1161]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Safety Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies must publish a notice in the <u>Federal Register</u> concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information and allow 60 days for public comment. This notice invites comments on a voluntary consumer survey entitled, "Food Safety Survey."

DATES: Submit either written or electronic comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Safety Survey--(OMB Control Number 0910-0345)--Reinstatement

I. Background

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), we are authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. The Food Safety Survey measures consumers' knowledge, attitudes, and beliefs about food safety. Previous versions of the survey were collected in 1988, 1993, 1998, 2001, 2006, and 2010. Data from the previous Food Safety Surveys and from this proposed survey will be used to evaluate two Healthy People 2020 objectives: (1) Increase the proportion of consumers who follow key food safety practices (Objective FS-5), and (2) reduce severe allergic reactions to food among adults with a food allergy diagnosis (Objective FS-4) (Ref. 1). Data from this survey will also be used to measure progress toward the United States Department of Agriculture's Food Safety Inspection Service's FY2011-FY2016 Strategic Plan goal of ensuring that, "Consumers, including vulnerable and underserved populations, adopt food safety best practices" (Ref. 2). Additionally, Food Safety Survey data are used to measure trends in consumer food safety habits including hand and cutting board washing, cooking practices, and use of food thermometers. Finally, data are used to evaluate educational messages and to inform policymakers about consumer attitudes about technologies such as food irradiation and biotechnology.

The proposed Food Safety Survey will contain many of the same questions and topics as previous Food Safety Surveys to facilitate measuring trends in food safety knowledge, attitudes, and behaviors over time. The proposed survey will also be updated to

explore emerging consumer food safety topics and expand understanding of previously asked topics. For example, recent papers in both the United States (Ref. 3) and Europe (Refs. 4 and 5) have pointed to changing epidemiology of listeriosis where adults over 60 years old have the highest rates of the illness. One reason for the increase in listeriosis rates among those over 60 years old could be increasing host susceptibility due to widened use of immunocompromising medications. We plan to include questions on the proposed survey to document the proportion of those over 60 years old who self-report taking a defined list of major immunocompromising medications. In conjunction with our established questions about safe food handling and eating potentially risky foods, the additional questions will expand our understanding of listeriosis among those over 60. Other new topics planned to be covered on the survey include: consumer understanding of mechanically tenderized beef, awareness of foodborne pathogens such as <u>Toxoplasma gondii</u>, and awareness of the risks associated with eating raw sprouts.

The methods for the proposed Food Safety Survey will be largely the same as those used with the previous Food Safety Surveys. One major difference is that, unlike the data collection mode for previous Food Safety Surveys that used only land telephone lines, the proposed survey will include cell phones in addition to landlines. A nationally representative sample of 4,000 adults (2,400 landline and 1,600 cell phone) will be selected at random for the telephone interviews. The survey will also include an oversample of Hispanics and Blacks to ensure a minimum of 400 each. Additionally, 50 non-respondents will be asked to participate in a short version of the survey from which we will conduct a non-response analysis. Participation in the survey will be voluntary. Cognitive interviews and a pre-test will be conducted prior to fielding the survey.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cognitive interview	75	1	75	0.083	6
screener				(5 mins.)	
Cognitive interview	9	1	9	1.	9
				(60 mins.)	
Pretest screener	45	1	45	0.0167	1
				(1 min.)	
Pretest	18	1	18	0.33	6
				(20 mins.)	
Survey screener	10,000	1	10,000	0.0167	167
				(1 min.)	
Survey	4,000	1	4,000	0.33	1320
				(20 mins)	
Non-response	125	1	125	0.0167	2
survey screener				(1 min.)	
Non-response	50	1	50	0.1	5
survey				(10 mins.)	
Total					1516

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on the Agency's prior experience with the Food Safety Survey.

II. References

- 1. U.S. Department of Health and Human Services, "Healthy People 2020 Improving the Lives of Americans," July 30, 2013. Available at http://www.healthypeople.gov/2020/default.aspx.
- 2. U.S. Department of Agriculture, Food Safety Inspection Service, "Strategic Plan FY 2011-2016," April 6, 2012. Available at

http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/strategic-planning/fy-2011-2016-strategic-plan/ct_index.

- 3. Pouillot, R., Hoelzer, K., Jackson, K.A., Henao, O.L. and Silk, B.J. "Relative Risk of Listeriosis in Foodborne Diseases Active Surveillance Network (FoodNet) Sites According to Age, Pregnancy, and Ethnicity," *Clinical Infectious Diseases*, 54(S5): S401-410, 2012.
- 4. Goulet, V., Hedberg, C., Le Monnier A. and de Valk, H. "Increasing Incidence of Listeriosis in France and other European Countries," *Emerging Infectious Diseases*, 14(5): 734-740, 2008.
- 5. Muñoz, P., Rojas, L., Bunsow, E., Saez, E., Sánchez-Cambronero, L., Alcalá, L., Rogríguez-Creixems, M. and Bouza, E. "Listeriosis: An Emerging Public Health Problem Especially Among the Elderly," *Journal of Infection*, 64: 19-33, 2012.

Dated: October 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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